

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 99-435V

December 5, 2006

Not to be published

STEPHANIE PHIPPEN,

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Petitioner,

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v.

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Entitlement; hepatitis B vaccine;
numb feet one week later;
MS causation by vaccine

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SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

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Respondent.

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Clifford J. Shoemaker, Vienna, VA, for petitioner.

Alexis A. Babcock, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

Petitioner filed a petition on July 2, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she received hepatitis B vaccine in March 1994 and had an adverse reaction. Petition, ¶ 2. The medical records show that petitioner's first

¹ Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

hepatitis B vaccination was administered on February 28, 1994. Med. recs. at Ex. 2, p. 7. She received MMR vaccine on March 15, 1994. Med. recs. at Ex. 2, p. 6. She was later diagnosed with cervical myelopathy and possibly multiple sclerosis. On April 11, 1994, petitioner received her second hepatitis B vaccination. Med. recs. at Ex. 2, p. 7.

Since one week is an appropriate temporal period for an adverse demyelinating reaction to occur after hepatitis B vaccine, on October 2, 2006, the undersigned issued an Order to Show Cause to respondent to show why this case should not be in damages.

On December 1, 2006, respondent filed an expert medical report from Dr. Gerald Winkler, a neurologist, stating that petitioner had probable MS. R. Ex. A. Dr. Winkler concludes that medical literature which he lists, but which respondent did not file, argues against a causal connection from hepatitis B vaccine, but Dr. Winkler states that the issue of causation remains controversial. Respondent asked the undersigned to rule on the record in respondent's Notice of Filing and Request for Ruling on the Record, filed December 1, 2006.

FACTS

Petitioner was born on January 28, 1964.

On February 28, 1994, petitioner received her first hepatitis B vaccination. Med. recs. at Ex. 2, p. 7.

On March 16, 1994, petitioner saw a chiropractor for tingling in her feet and legs which began one and one-half weeks earlier (putting onset at March 5th or 6th). Med. recs. at Ex. 4, p. 5.

On March 28, 1994, petitioner phoned her employer's health department to say she had noticed progressive tingling in both feet and then in her hand. The tingling's onset had been present for about three weeks (putting onset at March 7, 1994). Med. recs. at Ex. 2, p. 8.

On April 6, 1994, petitioner saw Dr. Ronald A. Cooper, a neurologist, because of paresthesias in her lower extremities over the prior four to five weeks, putting onset at the beginning of March 1994, and a Lhermitte's² phenomenon of more recent occurrence. Her neurological examination was essentially normal, except for some reflex asymmetry and a positive Lhermitte's sign. Med. recs. at Ex. 15, p. 14. About five weeks previously, petitioner noted some numbness in her feet that continued. *Id.* She inquired if she could get the second hepatitis B vaccination, and Dr. Cooper said yes on April 7, 1994. Med. recs. at Ex. 15, p. 7.

On April 7, 1994, an MRI of petitioner's brain showed multiple focal, punctate lesions of high signal intensity in the left middle cerebellar peduncle, right pons, and periventricular white matter adjacent to the frontal horns and atria of both lateral ventricles. These lesions were most consistent with demyelinating disease. Med. recs. at Ex. 15, p. 8.

Also on April 7, 1994, an MRI of petitioner's cervical spine showed focal swelling at the C2 and C3 levels. Med. recs. at Ex. 15, p. 9.

On April 9, 1994, Dr. Moore noted the results of the MRI scans suggesting a diffuse demyelinating process. This was the only attack petitioner had had and, therefore, Dr. Moore could not call it MS. Petitioner was prescribed Prednisone. Med. recs. at Ex. 15, p. 12.

On April 11, 1994, petitioner received her second hepatitis B vaccination. Med. recs. at Ex. 2, p. 7.

² Lhermitte's sign is "the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other diseases of the cervical cord." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1700.

On May 10-12, 1994, petitioner was neurologically evaluated at the Mayo Clinic. Dr. Emre Kokmen, a neurologist, diagnosed petitioner with subacute inflammatory demyelinating central nervous system disorder. Med. recs. at Ex. 16, p. 4.

It appears that petitioner did not take the third hepatitis B vaccination because she signed a release for her employer on September 28, 1994 refusing the vaccination (although a prior medical record said she received the third hepatitis B vaccination on August 27, 1994). Cf. Med. recs. at Ex. 2, p. 7 with pp. 12 and 14.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]" the logical sequence being supported by "reputable medical or scientific explanation[.]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had MS, but also that the vaccine was a substantial factor in bringing about her MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Respondent's expert, Dr. Winkler, in the instant action, states in his report that petitioner probably has MS. In Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), part of the Omnibus proceeding concerning hepatitis B vaccine and demyelinating diseases, the undersigned ruled that hepatitis B vaccine can cause MS, and did so in that case. The onset interval after hepatitis B vaccination was four weeks in Werderitsh.

In the Omnibus proceeding concerning hepatitis B vaccine and demyelinating diseases, respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute demyelinating reaction, would be a few days to three to four weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525 at *15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

Here, petitioner's onset of numbness began five to seven days after her first hepatitis B vaccination. This is an appropriate onset interval for causation.

The medically plausible medical theory and logical sequence of cause and effect were described in the testimony in Werderitsh. Petitioner has successfully proven all three criteria of Althen. This case is now in damages.

CONCLUSION

Petitioner has proved a prima facie case of causation in fact and is entitled to received compensation. The undersigned will hold a status conference soon with the parties to discuss the determination of damages.

IT IS SO ORDERED.

December 5, 2006

DATE

s/ Laura D. Millman

Laura D. Millman
Special Master